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Award Number: DAMD17-01-1-0238

TITLE: Tailored Communication to Enhance Adaptation across the Breast Cancer Spectrum

PRINCIPAL INVESTIGATOR: Suzanne M. Miller, Ph.D.

CONTRACTING ORGANIZATION: Fox Chase Cancer Center
Philadelphia, PA 19111

REPORT DATE: October 2004

TYPE OF REPORT: Annual

20050328 024

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

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REPORT DOCUMENTATION PAGE			Form Approved OMB No. 074-0188	
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503				
1. AGENCY USE ONLY (Leave blank)	2. REPORT DATE October 2004	3. REPORT TYPE AND DATES COVERED Annual (1 Oct 2003 - 30 Sep 2004)		
4. TITLE AND SUBTITLE Tailored Communication to Enhance Adaptation across the Breast Cancer Spectrum		5. FUNDING NUMBERS DAMD17-01-1-0238		
6. AUTHOR(S) Suzanne M. Miller, Ph.D.				
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Fox Chase Cancer Center Philadelphia, PA 19111 E-Mail: Suzanne.Miller@fccc.edu		8. PERFORMING ORGANIZATION REPORT NUMBER		
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012		10. SPONSORING / MONITORING AGENCY REPORT NUMBER		
11. SUPPLEMENTARY NOTES				
12a. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited			12b. DISTRIBUTION CODE	
13. ABSTRACT (Maximum 200 Words) Breast cancer represents a serious health concern for women, across the disease spectrum. First, despite the advances in technology used for intensive disease surveillance and innovative preventative options, interest in and utilization of these technologies is less than optimal, especially among low-income, African-American women. Second, among women who have completed cancer treatment, psychological after-effects that can have a negative impact on adjustment and adherence to further screening practices are prevalent. Finally, for those cancer patients whose disease has metastasized, clinically-relevant psychosocial adjustment problems need to be recognized and managed. It is for these reasons that research leading to improvements in quality of life throughout the disease spectrum is necessary. The Behavioral Center for Excellence, through the coordination of four projects, seeks to understand and evaluate psychosocial approaches for promoting psychological and physical adaptation to cancer risk, treatment, and survival. Each project systematically assesses and addresses barriers to, and facilitators of, adjustment and adherence and evaluates interventions designed for this cause. With support from four core facilities, the BCE has assembled a multi-disciplinary research team to conduct an interrelated set of studies that are theoretically-guided, thematically convergent, and synergistic in the impact on the behavioral aspects of breast cancer.				
14. SUBJECT TERMS Tailored Cancer Communications			15. NUMBER OF PAGES 57	
			16. PRICE CODE	
17. SECURITY CLASSIFICATION OF REPORT Unclassified	18. SECURITY CLASSIFICATION OF THIS PAGE Unclassified	19. SECURITY CLASSIFICATION OF ABSTRACT Unclassified	20. LIMITATION OF ABSTRACT Unlimited	

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DOD Progress Report, Project I
Understanding Breast Cancer Risk Assessment and Screening Behaviors Among the
Underserved

Suzanne M. Miller, Ph.D., Principal Investigator
Robert A. Schnoll, Ph.D., Co-Investigator
Andrea Barsevick, D.N.Sc., R.N., AOCN, Co-Investigator

Psychosocial and Behavioral Medicine Program
Division of Population Science
Fox Chase Cancer Center

INTRODUCTION

Breast cancer represents a serious health issue for African American women. Higher morbidity and mortality rates in this population may be due, in part, to lower uptake of breast cancer risk assessment and genetic counseling programs, as well as lower adherence to breast cancer screening recommendations (Miller & Champion, 1997). Yet, little information currently exists with respect to the psychosocial factors that facilitate participation in, and adherence to, available breast cancer risk assessment and screening programs. Further, there are no established intervention protocols to address the needs of this population. Guided by the research team's Cognitive-Social Health Information-Processing (C-SHIP) model, the overarching goal of Project 1 is to identify and assess barriers and facilitators to participation in breast cancer risk assessment and to adherence to breast cancer screening recommendations among African American women (Miller, 1995; Miller, 1996; Miller, Shoda, & Hurley, 1996; Miller, Fang, et al., 1999). These data will be used to develop and pilot test an intervention program to boost enrollment in breast cancer risk assessment programs and increase adherence to breast cancer screening guidelines among African American women.

The specific aims for Project 1 are as follows:

Aim 1: To develop a psychosocial assessment instrument, tailored to low-income African American FDRs of breast cancer patients, which assesses key psychosocial predictors of breast cancer surveillance behaviors (*Phase 1*).

Aim 2: To evaluate the psychometric nature of this questionnaire and to identify key longitudinal predictors (e.g., fatalism, attentional style) of participation in breast cancer risk assessment and of adherence to breast cancer screening recommendations (*Phase 2*).

Aim 3: To examine the feasibility and short-term impact of a cognitive-social intervention that is designed from Phase 1 and 2 data (*Phase 3*). Feasibility variables include number of recruitment calls needed, recruitment and attrition rates, level of satisfaction with the intervention, and degree to which women would recommend the program to others. Impact variables will include intention to pursue breast cancer risk assessment programs and adherence to breast cancer screening guidelines.

In Phase 1, we will conduct focus groups with African American FDRs of breast cancer patients ($N = 30$) to develop a psychosocial assessment of barriers and facilitators of participation in risk assessment programs and adherence to screening guidelines. We expect that low monitoring as well as a pattern characterized by low levels of knowledge about genetic risk and assessment programs, inaccurate risk perceptions, high fatalistic beliefs, low pros and high cons about risk assessment, and extremely high levels of emotional distress will emerge as important correlates of program interest and screening adherence. Phase 2 will be a longitudinal study with African American FDRs of breast cancer patients ($N = 100$) to evaluate the psychometric nature of this instrument and to identify prospective psychosocial predictors of intention/readiness to pursue breast cancer risk assessment and screening adherence. We hypothesize that high monitoring, as well as greater knowledge, higher risk perceptions, lower fatalism, higher pros and lower cons, and moderate levels of emotional distress will predict greater readiness to pursue risk assessment and higher levels of screening adherence. In Phase 3, we will examine the feasibility and impact

of an intervention for African American FDRs of breast cancer patients ($N = 30$) on interest in breast cancer risk assessment and screening adherence. We hypothesize that 75% of FDRs approached will agree to participate and that there will be a 20% attrition rate. Further, FDRs receiving this intervention will demonstrate greater interest in risk assessment program, as well as greater screening adherence.

Study findings will have applicability to enhancing current cancer prevention and control initiatives with underserved populations. This study will: 1) provide a theory-guided instrument for identifying women less likely to pursue risk assessment and adhere with screening guidelines; 2) identify a feasible, evidence-based approach to motivating breast cancer screening and participation in risk assessment programs among traditionally underserved women; and 3) provide information concerning the need for the simultaneous targeting and tailoring of interventions to promote decision-making about breast cancer assessment and adherence to surveillance behaviors. Overall, this study will provide important data for implementing breast cancer health-promotion interventions among underserved women on a broader scale.

BODY

During Year 1, we anticipated accomplishing Task 1 and initiating Task 2, as outlined in our Statement of Work. Task 1 involved refining a psychosocial familial risk questionnaire, tailored to low-income African American FDRs of breast cancer patients, that assesses key psychosocial correlates of interest in breast cancer risk assessment programs and adherence to breast cancer screening guidelines (*Phase 1*). We subdivided this task into the following sub-tasks:

- | | |
|---|--------------|
| a. Submit Protocol to Institutional Review Boards | (Month 1) |
| b. Recruit Focus Group Participants for Phase 1 | (Months 2-3) |
| c. Conduct Focus Groups | (Month 4) |
| d. Analyze Focus Group Data | (Month 5) |
| e. Develop Assessment Instrument for Phase 2 | (Month 6) |

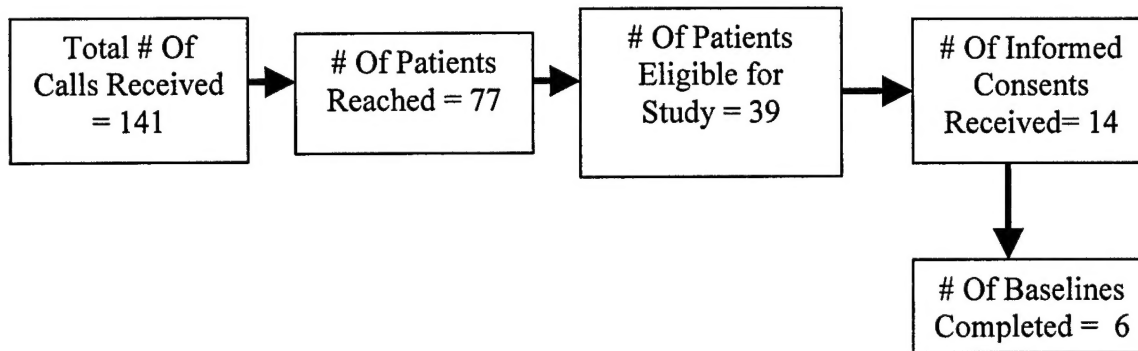
Task 2 involved evaluating the psychometric nature of the psychosocial familial risk questionnaire and identifying key longitudinal predictors of participation in breast cancer risk assessment and of adherence to breast cancer screening recommendations among female African American FDRs of breast cancer patients ($N = 100$; *Phase 2*). We subdivided this task into the following sub-tasks:

- | | |
|--|---------------|
| a. Submit Protocol to Institutional Review Boards | (Month 7) |
| b. Establish Recruitment Procedures/Staff Training for Phase 2 | (Month 8) |
| c. Recruit Participants, Conduct Longitudinal Study | (Months 9-30) |

To date, we have completed *Phase 1* of the overall project (i.e., Task 1, a-e). We have also submitted the protocol for *Phase 2* to the FCCC IRB for review and received approval (i.e., task 2, a) and began *Phase 2* data collection in the spring of 2004. Currently, recruitment efforts are being achieved by radio and newspaper ads that reach predominately African American women. We still may complete Task 2 by the pre-stated completion date of Month 30.

Below, in Figure 1, we summarize our recruitment efforts for phase 2 of this project.

Figure 1: Summary of Recruitment Efforts (phase 2)



KEY RESEARCH ACCOMPLISHMENTS OF PHASE TWO

- Attend and participate in monthly Center meetings.
- Created assessment tool from data gathered from Phase one.
- Created CATI system to conduct assessments over the phone.
- Advertised study in local newspapers and radio stations targeted at African American women.

REPORTABLE OUTCOMES

No outcomes to report at this time.

Below is a list of presentations and publications that are related to Project 1 activities.

- Presentations:

Fleisher, L., Schnoll, R., Miller, S., McKeown-Conn, N., and Brower, L. Women's self-reported knowledge about cancer risks, risk assessment programs and genetic testing: Preliminary findings. Paper Presented at the Annual Meeting of the American Society of Preventive Oncology, New York, N.Y., March, 2001.

Fleisher, L., Miller, S.M., McKeown-Conn, N., Brower, L., Schnoll, R., and Babb, J. Increasing Knowledge of Cancer Risk and Cancer Programs. Paper Presented at the Annual Meeting of the Era of Hope Breast Cancer Research Conference (sponsored by the Department of Defense), Orlando, FL, September, 2002.

Miller, S.M. Invited Keynote Plenary Speaker on: Behavioral contributions to breast cancer prevention and control. Part of Plenary Session on Breast Cancer Prevention. Era of Hope Breast Cancer Research Conference (sponsored by the Department of Defense), Orlando, FL, September, 2002.

Miller, S.M. Tailored communication to enhance adaptation across the breast cancer spectrum. Paper Presented at the Annual Meeting of the Era of Hope Breast Cancer Research Conference (sponsored by the Department of Defense). Orlando, FL, September, 2002.

- Publications:

Miller, S.M., Fang, C.Y., Diefenbach, M.A., & Bales, C. (2001). Tailoring psychosocial interventions to the individual's health information processing style: The influence of monitoring versus blunting in cancer risk and disease. In A. Baum & B. Andersen (Eds.), Psychosocial interventions in cancer. Washington DC.: American Psychological Association.

Miller, S.M., Sherman, K., Buzaglo, J., & Rodoletz, M. (2001) Monitoring-Blunting behavioral signatures in coping with health threats: The example of cancer. Psicologia della Salute, 3, 37-48.

Miller, S.M. (in press). Applications of the Monitoring Process Model. Applied Psychology: An International Review.

Miller, S.M. & Sherman, K.S. (in press). Cancer screening. In N. Anderson (Ed.) The Encyclopedia of Health and Behavior. CA: Sage Publications.

Sherman, K.S., Miller, S.M., Sheinfeld-Gorin, S. (in press) Psychosocial determinants of participation in breast cancer risk counseling programs and screening regimens among African American women. NY: Susan G. Komen Foundation and African American National Advisory Committee.

Miller, S.M., Bowen, D., & Croyle, R. (Eds.) Handbook of psychosocial approaches to cancer prevention. Washington, DC.: American Psychological Association, in preparation.

Miller, S.M. McDaniel, S., Rolland, J., & Feetham, S. (Eds.) Individuals, families, and the new genetics. New York: Norton Publications, in preparation.

CONCLUSION

Overall, we have successfully completed Phase 1 of this project, namely the focus group interviews with 27 participants. Phase 2 recruitment of this project, although it began somewhat behind schedule, has shown promise with radio and newspaper ads placed and interest in the study seems favorable. We expect that we will achieve our recruitment goals with this uniquely challenging, and understudied population and successfully complete the entire study as proposed.

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Miller, S. M. (1996b). Monitoring and blunting of threatening information: Cognitive interference and facilitation in the coping process. In I. G. Sarason, Pierce, G.R., & Sarason, B.R. (Ed.), Cognitive Interference: Theories, methods, and findings. (pp. 175-190). NJ: Lawrence Erlbaum.

Miller, S.M., Fang, C.Y., Manne, S.L., Engstrom, P.E., Daly, M.B. (1999). Decision making about prophylactic oophorectomy among at-risk women: Psychological influences and implications. Gynecologic Oncology, 75, 406-412.

Miller, S.M., Shoda, Y., & Hurley, K. (1996). Applying cognitive-social theory to health-productive behavior: Breast self-examination in cancer screening. Psychological Bulletin, 119, 70-94.

DOD Progress Report, Project II
A Teachable Moment within the Family: From Concept to Community

Mary B. Daly, MD, Principal Investigator
Dr. Suzanne M. Miller, Ph.D., Co-Investigator
Samuel Litwin, Ph.D., Statistician

Psychosocial and Behavioral Medicine Program
Division of Population Science
Fox Chase Cancer Center

INTRODUCTION

Despite advances in cancer detection and treatment, breast cancer remains the most common cancer among women and accounts for a staggering number of lives lost per year. Knowledge about both the genetic and environmental causes of breast cancer is being translated into tailored screening protocols, chemoprevention approaches, and diet and lifestyle modifications, targeted to women at highest risk. First-degree relatives (FDRs) of breast cancer patients comprise a particularly appropriate group among whom to concentrate efforts to maximize risk reduction and early detection. Although a family history of breast cancer is a well-known risk factor, studies have shown that many women are unsure of their risk status and are often unaware of the cancer prevention strategies that may be appropriate for them. The diagnosis of breast cancer in a close relative may provide the ideal opportunity, a "teachable moment," to reach at-risk family members to address their needs and concerns and make available risk assessment and counseling programs. The goals of the proposed study are to test a health communication message personalized to a set of demographic, clinical and psychosocial factors and timed to capitalize on the heightened awareness of breast cancer risk attendant to the recent diagnosis in an FDR. The project represents a partnership between a comprehensive cancer center (FCCC) and a series of community hospitals (FCCC Network affiliated sites) in an effort to enhance dissemination of state-of-the-art cancer prevention and control strategies to the community setting. Affected patients identify at-risk relatives at each site, and permission is sought to contact them by phone for participation in the study. Study participants are randomized to either a personalized message keyed to age, risk level, family history, screening behaviors and attention style, or to a general, non-personalized health message. Surveys are administered to adult daughters and sisters at two time points -- baseline and 12 months later -- in order to capture both newly formed intentions to seek cancer risk information and counseling, adopt lifestyle changes, and/or initiate appropriate surveillance regimens, and the actual action upon these intentions. The C-SHIP model of cognitive-affective processing of health threats is used as the theoretical framework for this study.

Aim 1: To develop and evaluate a theory-driven message tailored to a set of relevant variables including monitoring attentional style to enhance participation in FCCC's Family Risk Assessment Program (FRAP). The hypotheses are that patients exposed to this tailored message will be more likely to 1) seek risk assessment and counseling through FRAP, and 2) adopt risk-reducing behaviors than those patients who receive a non-tailored risk message.

Aim 2: To examine the moderating effects of individual differences in educational level, relationship to the patient, and level of anxiety and cancer-related distress.

BODY

The focus in the project during the past year has been recruitment of participants and ongoing capture of data, as well as the finalization of the 12-month follow up Health History Questionnaire (HHQ). The 12-month follow up HHQ was pilot tested to assess content validity and determine the length of time it takes to complete the survey over the telephone. The FCCC IRB and the Department of Defense approved the final survey. The project team and the Informatics Core worked to develop the ability to capture these data in our database. We began

administering the 12-month follow up HHQ in March 2004. As of September 30, 2004 40 participants have completed the 12-month follow up interview and thus, the study.

Both the patient and relative consent forms were substantially revised to meet a mandate put forth by the FCCC regarding readability of consent forms. As of March 1, 2004, the FCCC IRB requires that all consent forms submitted for initial and ongoing review be at a readability level of grade 8.0 or lower, prior to addition of drug/device names and defined medical terms. Readability level is assessed using the Flesch-Kincaid method included as part of the spelling/grammar function in MS Word. As part of the ongoing review process at FCCC, we rewrote both consent forms using a new template provided by the IRB. Both consent forms are now written at an $\leq 8^{\text{th}}$ grade reading level to enhance understanding for patients and their relatives giving consent to participate in the study.

An additional FCCC Network Hospital (VirtuaHealth) obtained approval by the local and FCCC IRBs as well as the Department of Defense during this year. The Project Coordinator met with the staff at Virtua to discuss logistics and start up procedures in order for recruitment to begin at that site. Discussions with additional FCCC Network and affiliated hospitals continue (Geisinger Medical Center, ChristianaCare Health System) and the sites are at various stages of assessing interest in conducting the study at their institutions. Reading and Paoli continue the annual review process at their sites. However, due to staffing constraints neither site has recruited any participants. This is a result of limited staff ability at the sites to identify breast cancer patients in the local medical practices. We are actively working with these sites to identify viable recruitment strategies in their communities.

The following is a description of the research accomplishments associated with each Task as outlined in the approved Statement of Work.

During Year 3, we completed outstanding sub-tasks within Task 1, Study start-up phase, and continued with other sub-tasks as follows:

- | | |
|---|--------------|
| b. Finalization of survey instruments | (months 1-3) |
| c. Finalization of recruitment strategies | (months 1-3) |
| d. Training of study personnel | (months 4-6) |

Finalization of survey instruments was completed with the approval of the 12-month follow up survey. As described above, the instrument was pilot tested as part of the development process. This questionnaire is administered to participants 12 months after the telephone counseling session is completed.

Sub-task c.-Finalization of recruitment strategies, is an ongoing, dynamic process as we continue to explore viable strategies at both FCCC and the network sites. One example of a new recruitment strategy that was implemented during this period was placing an IRB approved recruitment article in the semiannual Family Risk Assessment Program newsletter. We have also set up a "recruitment table" during clinic times when breast cancer patients are seen at FCCC. The study brochure is displayed at this table and study staff is available to answer questions as potential participants approach the table. The Project Manager continues working with the

network sites to facilitate approval of the study and to try and establish viable recruiting strategies in the face of very limited human resources at the sites.

Sub-task d.-Training of the two Health Educators conducting the telephone counseling sessions continues. The study team has met on an ongoing basis to identify problems, develop support tools and streamline the scheduling and implementation of the counseling sessions. The list of frequently asked questions (FAQs) and answers continues to be updated with input from the counselors that evolves during their sessions with study participants. FCCC instituted a new electronic medical records system which required additional training of study personnel. This system involves a greater time commitment on the part of the staff in determining which patients to approach about their relative's participation in the study. We will continue to utilize this system and identify and refine the best practices to maximize our recruitment potential.

We continued working on Task 2, Conducting a prospective, randomized trial. This task was subdivided into sub-tasks that are being completed on an ongoing basis.

- | | |
|---|----------------|
| a. Identification of FDRs | (months 7-30) |
| b. Mailing of pre-call letter | (months 7-30) |
| c. Baseline telephone interview | (months 7-30) |
| d. Follow-up letter | (months 7-30) |
| e. Delivery of experimental and control sessions | (months 8-31) |
| f. Quality control tests performed on a randomized sample of sessions | (months 8-31) |
| g. Follow up print materials mailed to participants | (months 8-31) |
| h. Informatics Core to complete data entry and management | (months 7-44) |
| i. Conduct 12-month follow-up phone call | (months 20-44) |

Identification of FDRs continues through use of the new Clinical Information System at FCCC. This system replaces the prior Health Information Management System. Once the staff was trained in the use of this new system, we continued to identify breast cancer patients and assess whether they met the time from diagnosis criteria. This system is more complex than our previous system, and has required a great deal more time to identify potential patients. Additionally, approved study brochures are distributed to all new breast cancer patients coming to FCCC for their initial visit. Brochures are also placed around the center in high traffic areas, as well as displayed at various patient education events on campus. As described above, study staff also began participating in a recruiting table that is set up during the hours of the Breast Evaluation Clinic to display information about the project and answer questions for patients being seen in the clinic that day. Additionally, a recruitment article about the study was included in the Family Risk Assessment Program semiannual newsletter. Once the patients are identified, the study staff has continued contacting them to set up a time to meet when they are scheduled to be at FCCC for a routine appointment. Once we briefly introduce the study to the patient over the phone and preliminarily assess interest and eligibility, a time and place to meet in person is arranged. A member of the study staff then meets with the patient, explains the study, obtains informed consent and assists the patient in completing the Relative Information form to identify their eligible FDRs (**subtask a**).

Pre-call letters are then mailed to the FDR (**subtask b**) along with the Relative Informed Consent and HIPAA forms to introduce the study. If the FDR does not call to decline participation within a specified timeframe, the Informatics Core generates a contact log. This log flags the date for a member of the study staff to follow up on the pre-call letter with a phone call to assess the FDRs interest in participating in the study. Once we assess eligibility and the FDR has agreed to participate, the study staff obtains informed consent from the participant and asks her to sign and return the informed consent and HIPAA authorization forms.

Another phone call is scheduled for the baseline telephone interview (**subtask c**) at which time the baseline HHQ is completed over the telephone. The survey takes between 20-45 minutes to complete. The variability in time is mostly due to the size of the family and the accompanying family history information being collected. This call only takes place once the signed forms are received back by the study staff. A photocopy of the signed consent and HIPAA forms are then sent to the FDR for their records. Another call is scheduled within a few weeks of the baseline interview for the delivery of the counseling session.

Once the interview is completed, a follow up letter (**subtask d**) is generated by the Informatics Core and provided to the study staff. This letter confirms the date and time for the upcoming telephone counseling session and is sent along with a small monetary reimbursement to the participant thanking her for her time and interest in participating. The baseline HHQs are entered into the database and the participant is randomized to either the experimental or control groups. A tailored script is generated for each woman in the experimental group based on several variables captured during the baseline telephone interview. These variables include attention style, family history/risk level and compliance with breast cancer screening. For women in the control group, a general health information script is generated covering such topics as diet, dietary supplements and exercise. The Project Coordinator reviews each script to ensure that the tailoring algorithm is correctly applied to each script and that the text is personalized for the specific participant.

The experimental and control counseling sessions (**subtask e**) are completed by two Health Educators trained to administer the intervention. The sessions take from 10-30 minutes and conclude with a description of the local Family Risk Assessment Program with contact information on how to enroll. Participants are given an opportunity to ask questions throughout the session and are given additional resources (e.g. NCI website, Cancer Information Service) by the counselor as appropriate to the individual situation.

A subset of eleven of these sessions was audiotaped with permission from the participant and the Project Manager reviewed these tapes to assess quality control of sessions (**subtask f**). Sessions are being delivered appropriately and the format of the scripts encourages interaction between the participant and the counselor. The counselor notes participants' comments throughout the session and completes an evaluation form at the end of each session. The Project Coordinator reviews all evaluation forms and addresses any problems or questions that arose during the session.

Follow up print materials are then mailed to participants (**subtask g**) within two weeks after the completion of the counseling sessions. Also included in this mailing is a brochure and invitation

to enroll in FRAP for more in-depth counseling and education about their risk for developing breast cancer.

The Informatics Core staff enters and manages the data (**subtask h**) on an ongoing basis. Study staff continues to meet with the Informatics Core on a regular basis to ensure that participant data are being captured and project timelines are being met. Several project management reports were developed to assist the Project Coordinator with tracking progress of the study. Each study event is recorded through use of a checklist and data entry process on an ongoing basis. Data from the baseline and follow up HHQs are entered into the database by Informatics Core staff. The study staff enters study checklists which capture each study event as every participant completes it. Additionally, appointments for telephone sessions are scheduled and managed utilizing an MS Outlook calendar.

The 12-month follow up Health History Questionnaire was finalized and approved by the FCCC IRB and the Department of Defense during this period. We began administering the survey over the telephone in March, 2004 (**subtask i**) as participants reached the 12 month mark after their counseling session. The Informatics Core generates a call log after a participant has been in the study for 11 months, and study staff begins to contact participants to complete the follow up interview in the ensuing weeks. The follow up HHQ takes approximately 30 minutes to complete over the telephone. Once this interview is completed, the participant has completed the study.

Task 3, to conduct data analyses on all data collected and to present/publish findings is not applicable to the Year 3 Report. However, the subtasks are as follows:

- | | | |
|----|--|----------------|
| a. | Statistical analyses of data obtained | (months 40-46) |
| b. | Publicize study findings | (months 43-48) |
| c. | Prepare final report for granting agency | (months 46-48) |

KEY RESEARCH ACCOMPLISHMENTS

- Obtained informed consent on 44 subjects and completed telephone counseling sessions with 47 subjects during the past year, for a total of 109 participants providing consent and 95 counseling sessions conducted from study's inception.
- Attended and participate in monthly Center meetings.
- Finalized the 12-month Health History Questionnaire and worked with the Informatics Core to complete development the database
- 12-month follow up Health History Questionnaires were administered to 40 subjects, completing their participation in the study
- Explored new recruiting procedures for identifying eligible breast cancer patients and their first-degree relatives.
- Ongoing communication with FCCC Network site staff (N=5) to coordinate study approval and start up activities at each site.

REPORTABLE OUTCOMES

N/A

CONCLUSION

Subject recruitment continued at FCCC during the past year. The 12-month follow up Health History Questionnaire was finalized, approved and put into use during this period. We have continued to identify and refine recruitment procedures at both FCCC and network sites. We have established a consistent internal queue of women based on the appropriate time from diagnosis (e.g. 6-12 months) providing us with a steady flow of potential subjects to approach for participation in the study. Uptake of the study at the network sites has been much slower than anticipated. This is due to lack of local staff time to identify eligible breast cancer patients to enable recruitment of relatives. We have identified the most effective recruitment strategies at FCCC and are using these as a model with the sites. We will continue to work with the network sites to identify additional opportunities for recruiting participants locally. Improved recruitment is anticipated in the coming year, with strong support of the study at the newest site gaining approval, and by incorporating creative recruitment strategies in the community.

REFERENCES

N/A

DOD Progress Report, Project III
Facilitating Re-entry Following Treatment for Primary Breast Cancer

Dr. Suzanne M. Miller, Ph.D., Principal Investigator
Dr. Joanne S. Buzaglo, Ph.D., Co-Investigator
Andrea Barsevick, D.N.Sc., R.N., AOCN, Co-Investigator
Dr. Lori J. Goldstein, MD, Co-Investigator
Dr. Mary Cianfrocca, MD, Co-Investigator

Psychosocial and Behavioral Medicine Program
Division of Population Science
Fox Chase Cancer Center

INTRODUCTION

As screening and surveillance for breast cancer has increased and treatment improved, the number of survivors of primary breast cancer has increased substantially (ACS, 2000; Pandey et al., 2000). The 5-year relative survival rate for localized breast cancer has increased from 72% in the 1940s to 96% today (ACS, 2000). Further, 71% of women diagnosed with breast cancer survive 10 years, and 57% survive 15 years (ACS, 2000). As the number of cancer survivors has increased, so too has the concern for the psychosocial adaptation of cancer survivors (e.g., Andersen, 1994; Ganz et al., 1996; Ganz et al., 1998; Gotay & Muraoka, 1998; Kornblith, 1998; Kurtz, Wyatt, & Kurtz, 1995; Schag et al., 1993; Wyatt & Friedman, 1996; Weitzner et al., 1997). However, little research has focused on easing the transition of individuals with early stage breast cancer from active treatment to follow-up care, referred to as the re-entry phase; even less research has focused on how individual differences moderate the process of adjustment to the challenges of survivorship (see Andersen, 1994; Helgeson et al., 2000). Guided by the Cognitive-Social Health Information Processing model (Miller, Shoda, et al. 1996; Miller, Mischel, et al. 1996), the primary objective of the proposed study is to develop and evaluate a tailored Cognitive-Affective Processing (CAP) intervention to facilitate psychosocial adjustment at re-entry following adjuvant treatment for primary breast cancer (Miller, 1995; Miller, 1996; Miller, Shoda, & Hurley, 1996; Miller, Fang, et al., 1999).

The specific aims for Project 1 are as follows:

Aim 1: To develop and evaluate a theory-based, individually tailored Cognitive-Affective Processing (CAP) intervention to facilitate re-entry following adjuvant treatment for primary breast cancer.

Aim 2: To examine the moderating effects of individual differences in attentional style (i.e., high vs. low monitoring) on the impact of the proposed intervention.

To reach the primary objective of the proposed study, three focus groups were conducted during Phase I of the study (months 1-6). Eighteen women from the target population (early stage, primary breast cancer patients) participated in the focus groups. The goal of the focus groups was to facilitate the development and refinement of the CAP intervention and the measures. The first two focus groups were designed to explore and assess the challenges confronted by the study population during the transition from being an active patient in treatment to a breast cancer survivor, i.e., the 're-entry' phase. Specifically, focus group participants were asked to discuss their perceived risk, expectancies and beliefs, values and goals, emotions, and coping strategies regarding their transition into 'survivorship'. Specific areas targeted included their cognitive-affective responses to cancer recurrence, cessation of treatment, sexuality, body image, and personal relationships. This information was used to further refine the intervention and measures. The final focus group was designed to obtain final suggestions for the improvement of the intervention and the battery of measures.

During Phase II, women ($N=300$) who have been diagnosed with Stage 0, I, or II breast cancer and are being treated at Fox Chase Cancer Center (FCCC) will be contacted for participation. Potential participants will be identified through the scheduling office at the Breast Cancer Evaluation Clinic at FCCC and will be recruited near the completion of their adjuvant treatment.

After they have been given a description of the study, participants who meet eligibility criteria and wish to participate will be asked to sign a consent form. Consenting participants will be randomized into either the intervention or control condition. All consenting participants will receive the intervention or control session during a post-adjuvant treatment follow-up medical visit. A booster session will be given two-weeks post-counseling intervention. All participants will be assessed via mail at one, six and twelve months post-intervention. The health educator will contact the participant by phone to collect follow-up data in the event that participants do not return the questionnaires within 2 weeks.

BODY

During Year 1, the plan was to complete Task 1 and initiate Task 2, as outlined in our Statement of Work. Task 1 involves coordinating with the Communications Core in the testing and subsequent refinement of the cognitive-affective intervention designed to facilitate "re-entry" into the post-treatment phase of breast cancer for early stage breast cancer patients. This was to be accomplished through the use of focus groups to test both the intervention and the measures, with the Communications Core leading the process. The specific aims of Task 1 are to:

- | | |
|--|--------------|
| a. Recruit Focus Group Participants for Phase I | (Month 1-2) |
| b. Conduct Focus Groups | (Months 2-3) |
| c. Analyze Focus Group Data | (Month 3-4) |
| d. Refine Interventions/Measures | (Month 4-5) |
| e. Conduct Focus Groups to Evaluate Refined Interventions/Measures | (Month 5) |
| f. Establish Recruitment Procedures/Staff Training | (Months 5-6) |

Over the course of the past year, the responses from the three focus groups, in addition to comments and suggestions made by an external review committee, were used to refine the barriers intervention. While the intervention still addresses the cognitive-affective mediating units of the participants, there is now a better sense of understanding of the primary concerns and issues of breast cancer survivors as well as the barriers to re-entry, which will be thoroughly addressed in the intervention session, with particular attention given to focus group participants' preferences for the timing of the delivery of the counseling intervention and the method by which the intervention will be delivered. Specifically, the intervention will be delivered soon after the completion of adjuvant treatment with follow-up assessments conducted at the one-, six-, and twelve-month time points. The intervention draws heavily from the NCI publication, *Facing Forward*, and is consistent with its philosophy of taking an active role in recovery in combination with accepting changes that are beyond the patient's control. Further, the intervention provides strategies for coping with barriers to the re-entry phase of recovery and participants will receive additional resources for dealing with their concerns. The FCCC IRB approved revisions to the original protocol in May 2004. The approval documents were then submitted to the DOD for review and in August 2004 the DOD made further recommendations to the amendments. The recommendations from the DOD were submitted to the FCCC IRB in October 2004. These changes will again go to the DOD upon FCCC IRB approval.

Because the information obtained from three focus groups was adequate to modify the barriers intervention, an amendment was submitted to conduct a pilot study ($N=20$) in place of the fourth

focus group. This modification was also approved in May 2004. The pilot study will provide a realistic evaluation of both the initial assessment and the revised intervention in terms of their thoroughness, applicability and feasibility. This will be a cost- and time-efficient way to make final improvements to the protocol in that participants will be given the opportunity to make suggestions on any issues that they feel are not adequately addressed.

Task 2, which was to be initiated during year 1 and continued into year 3, involves conducting the revised randomized trial ($N=300$) comparing the Cognitive-Affective Preparation (CAP) protocol designed to address the barriers to "re-entry" into the post-treatment phase of breast cancer for early stage breast cancer patients. The CAP intervention will be compared with a General Health Information (GHI) control to equate for time and attention. The specific aspects of Task 2 are to:

- | | |
|---|---------------|
| a. Recruit Participants, Randomize to Treatments,
Test Interventions | (Months 7-30) |
| b. Participants Eligible for Genetic Testing will be
Referred to the Genetic Susceptibility Testing
Laboratory Core | (Months 7-30) |

Task 2 will begin upon completion of the pilot study. Final DOD approval of the revised protocol is pending. Recruitment for the pilot study portion of this study will begin upon approval. Once 20 pilot participants have completed the baseline assessment and the intervention, we will begin recruitment for Task 2.

Our team recently attended a consultation meeting with the Informatics Core to initiate the database edifice. Preliminary data collection procedures were discussed as well as the facility's role in handling these data. At this point, the role of the Informatics Core is minimal, however, further arrangements will be made as the study progresses.

Task 3, which was scheduled to begin this year, involves conducting data analyses on all data collected and presenting/publishing findings. However, due to delays in the revision and approval of the intervention, this task has not been initiated. To allot for the extra time that will be needed to complete task 3, we will request a no-cost extension to continue this study in July 2005 so that this request may be processed 30 days before the scheduled completion of the study.

- | | |
|--|----------------|
| a. In collaboration with the Informatics Core
Statistical Analyses of Data Obtained | (Months 31-42) |
| b. Publicize Study Findings | (Months 43-48) |
| c. Prepare Final Report for Granting Agency | (Months 43-48) |

KEY RESEARCH ACCOMPLISHMENTS

- Continue to attend and participate in monthly Center meetings.
- Revised the initial barriers intervention based on information obtained from three focus groups.

- Submitted revisions to the FCCC IRB and received approval of these revisions in May 2004.
- Submitted the FCCC IRB approved revisions to the DOD, which the DOD tentatively approved in August 2004 contingent on the FCCC IRB approval of three changes recommended by the DOD. These changes have been made and were submitted to the FCCC IRB in October 2004 and approval is pending. Once approved, they will be sent to the DOD for review.
- Preliminary data collection procedures have been established with the Informatics Core to initiate the database edifice with further plans to be developed as necessary.

REPORTABLE OUTCOMES

No new data have been collected during this research period.

Below is a list of presentations and publications that are related to Project 3 activities.

- Presentations:

Miller, S.M., Schwartz, M. Invited Presentation at the Cancer Genetics Studies Consortium Consensus Meeting. Paper on screening/prevention practices of individuals at risk: Building bridges from tantalizing research findings to future directions. Alexandria, VA, October, 2003.

Miller, S.M. 53rd Annual Meeting of the American Society of Human Genetics. Paper presented on: Genetic predisposition: Individual evaluations of risk. Part of Invited Session on: Genetic Risk Communication in Theory and Practice: Exploring the Possibilities. Los Angeles, CA. November, 2003.

Miller, S.M. Invited Speaker. Japan Foundation for Aging and Health. Mental Support for patient's with cancer. Kobe, Japan, February 2004.

Miller, S.M. Invited Speaker. University of the Sacred Heart. Presentation: Behavior and Cancer. Tokyo, Japan, February 2004.

Miller, S.M., Rodoletz, M., Daly, M.B., Roussi, P., Buzaglo, J., Godwin, A., Malick, J., Wang, H., Montgomery, S., & Spoltore, J. Impact of a Cognitive-Affective Preparatory intervention among high risk women undergoing breast/ovarian genetic testing. Poster presented at the 28th Annual Meeting of the American Society of Preventive Oncology, Bethesda, Maryland. March, 2004.

Miller, S.M., Roussi, P., Rodoletz, M., Daly, M.B., Sherman, K.A., Diefenbach, M.A., Buzaglo, J., & Godwin, A. Impact of an Enhanced Counseling Intervention Among High-Risk Women Undergoing Breast/Ovarian Genetic Testing. Poster presented at the Annual Meeting of the Society of Behavioral Medicine. Baltimore, Maryland. March, 2004.

Miller, S.M. Invited Speaker. The Second Annual Lynne Cohen Foundation Symposium on Women's Cancer: Defining the Roles of Genetics and the Environment. Presentation on: "Factors/Issues in Clinical Decision Making." New York, NY. April, 2004.

Miller, S.M., Stanton, L., Rodoletz, M., Daly, M.B., Sherman, K.A., Roussi, P., Wang, H., Godwin, A., Spoltore, J., Montgomery, S., & Michael, J. Facilitating health behaviors among women undergoing BRCA 1/2 testing. Presented at the Annual Meeting of the American Society of Clinical Oncology, New Orleans, Louisiana, June 2004.

Miller, S. M. 8th International Congress of Behavioral Medicine. Paper on: Tailoring Monitoring vs. blunting in the preparation for stressful medical procedures. Part of Invited Symposium on: Psychological Preparation for Medical Intervention. Mainz, Germany. August, 2004.

- Publications:

Miller, S.M. & Sherman, K.A.A. (2004). Cancer screening. In N. Anderson (Ed.) The Encyclopedia of Health and Behavior. CA: Sage Publications.

Sherman, K.A.A., Montrone, M., & Miller, S.M. (2004). Infertility. In N. Anderson (Ed.). The Encyclopedia of Health and Behavior. CA: Sage Publications.

Miller, S.M., Bowen, D. J., Campbell, M.K., Diefenbach, M.A., Gritz, E.R., Jacobsen, P.B., Stefanek, M., Fang, C.Y., Lazovich, D., Sherman, K.A., Wang, C. (2004). Current research promises and challenges in behavioral oncology: Report from the American Society of Preventive Oncology Annual Meeting. Cancer Epidemiology, Biomarkers and Prevention, 13, 171-180.

Miller, S.M. (in press). Applications of the Monitoring Process Model. Applied Psychology: An International Review.

Sherman, K.A.A., Miller, S.M., Sheinfeld-Gorin, S. (in press). Psychosocial determinants of participation in breast cancer risk counseling programs and screening regimens among African American women. In: Breast Cancer in African American Women. NY: Susan G. Komen Foundation and African American National Advisory Committee.

Schnoll, R.A., Miller, S.M., Wang, H., Babb, J.S., Cornfeld, M.J., Higman-Tofani, S., Henigan-Peel, T., Balshem, A., Slater, E., Ross, E., Boyd, S., Engstrom, P.F. (in press). Change in worksite behavior following cancer risk feedback: A pilot study. American Journal of Health Behavior.

Katz, M.L., Ruzek, S.B., Miller, S.M., Legos, P. (in press). Gender differences in patients needs and concerns to diagnostic tests for possible cancer. Journal of Cancer Education.

Miller S.M., Roussi, P. (in press). Psychosocial Factors Involved in Genetic Testing Decisions and Behaviors. Hellenic Journal of Psychology.

Miller, S.M., et al. (in press) Information processing in breast/ovarian genetic risk. Health Education and Behavior.

Miller, S.M., Fleisher, L., Schnoll, R.A., Rodoletz, M., Razabonni, E., et al. (in press) Facilitating Breast Cancer Genetic Counseling Referral through Information, Preparation, and Referral, Journal of the National Cancer Institute.

CONCLUSION

Upon DOD approval of all protocol revisions, we will begin recruitment for the pilot study portion of the study. Full implementation of Phase II will begin after we have recruited and collected baseline information for 20 participants as well as conducted the barriers intervention for these participants. As these processes are underway, we anticipate no further major obstacles and expect no major delays in the further progress of this project.

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DOD Progress Report, Project IV
Communication Skills Versus a Supportive Therapy Intervention for Women with Metastatic
Breast Cancer

Dr. Sharon Manne, Ph.D., Principal Investigator
Dr. Robert Schnoll, Ph.D., Co-Investigator

Psychosocial and Behavioral Medicine Program
Division of Population Science
Fox Chase Cancer Center

INTRODUCTION

Excluding skin cancers, breast cancer is the most common cancer diagnosed in American women. Recent advances in early detection and treatment have resulted in higher cure rates for breast cancer. Unfortunately, approximately 6% of breast cancer patients develop metastatic disease (stage IV). For the majority of women diagnosed with metastatic breast cancer, median survival is approximately 18 to 24 months with systemic chemotherapy. The overall five-year survival rate for women with stage IV breast cancer is 21.3%. Thus, although a cure is not achieved for most patients, treatment improvements have made it possible for women to survive for relatively long periods of time with stable disease. Consequently, symptom relief and improvement in quality of life are critical therapeutic goals for this population.

The specific aims for Project 4 are as follows:

Aim 1: To compare the effectiveness of a communication and support skills intervention versus a supportive therapy intervention on the quality of life of women with metastatic breast cancer.

Aim 2: To explore the effects of individual differences (e.g., ambivalence over emotional expression), treatment expectancies, social support and coping on the impact of the interventions.

This is a multi-site study, with prospective subjects being identified at the Fox Chase Cancer Center (FCCC), Cooper Health System Division of Hematology/Oncology, Temple Cancer Center, and Bryn Mawr Hospital (BMH) of the Main Line Health System. On-site physicians regularly provide the research assistant with a list of eligible patients who have given permission to be contacted for this study. Eligible participants are mailed a letter describing the study. Patients are approached and contacted in person by the Research Study Assistant during a clinic appointment, and the study is described in more detail. If the participant is interested in participating, informed consent will be obtained at that time. After obtaining written informed consent, the pre-intervention assessment packet is administered.

The study design is a randomized clinical trial with two study conditions: 1) Communication and Support Skills intervention, 2) Supportive counseling intervention. Patients are assigned to one of these conditions after the initial packet has been completed. The intervention programs are administered in an individual format with six in-person sessions and one telephone follow-up. Assignment is stratified into groups having low or high baseline psychological distress as determined by the Beck Depression Inventory.

The goal of this study is to determine whether an intervention targeted to women with breast cancer can impact their psychological distress. We have utilized a structured, CBT-oriented intervention that teaches effective communication and support skills because this type of intervention will assist patients in obtaining support from their existing support networks (rather than from other patients). Prior studies have suggested that deficits in support from partners and a lack of open engagement with partners are particularly problematic for female, late stage patients and among metastatic breast cancer patients. We have selected supportive psychotherapy as a comparison condition because this intervention will not provide skills, but will provide emotional support. In addition, this condition will provide a control for the non-specific effects of therapy (therapeutic bond, treatment expectancies, time and attention spent on the patient). We

will examine the role of these non-specific factors in treatment outcome. We also will assess adherence to treatment protocol and treatment discrimination, which have been ignored in prior research. By focusing an individual difference variable (lack of support) that has been shown to predict a beneficial outcome for interventions, we may be more likely to elicit a response to treatment that has not been consistently found in prior studies of metastatic breast cancer patients.

BODY

Below are the specific tasks to be accomplished, as originally outlined in the Statement of Work, in the context of this Project 4. In addition, we have provided estimates of the amount of time it will take to complete these tasks.

Task 1 (Months 1-5):

To refine the intervention manual for the support skills intervention and train psychotherapists in administration of both interventions.

- | | |
|--|--------------|
| a. Recruit Focus Group Participants | (Months 1-2) |
| b. Conduct Focus Groups | (Month 3) |
| c. Analyze Focus Group Data | (Month 4) |
| d. Train therapists in both conditions | (Month 5) |
| e. Prepare study questionnaires, recruitment materials, materials for therapists | (Month 5) |

Task 2 (Months 6-47).

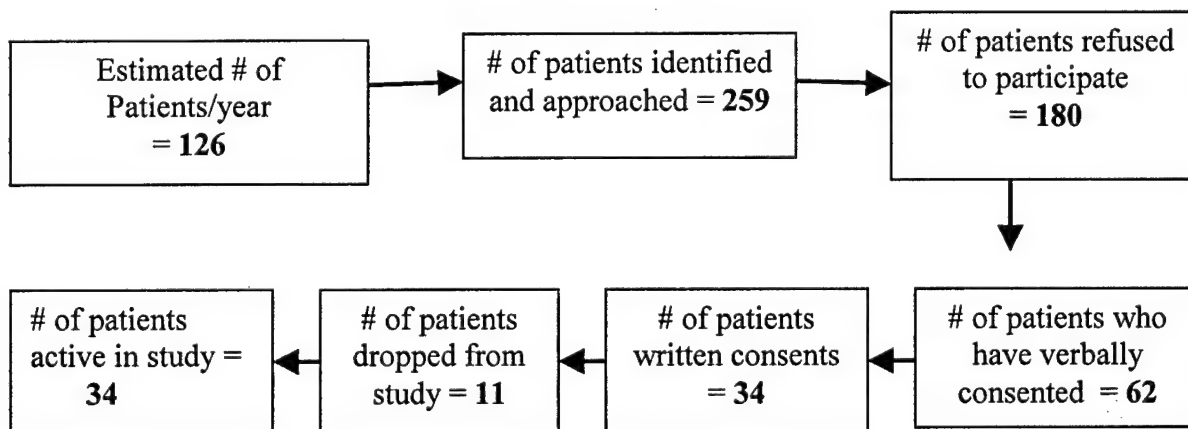
- | | |
|---|---------------|
| a. Recruit participants | (Months 6-42) |
| b. Administer study questionnaires | (Months 6-42) |
| c. Conduct intervention sessions | (Months 4-43) |
| d. Regular therapist supervision meetings | |
| (Months 4-43) | |
| e. Enter study data | (Months 4-47) |
| f. Conduct follow-up assessments | (Months 4-47) |
| g. Treatment integrity checks | (Months 4-47) |

Based upon previous experience, Project 4 staff determined that focus groups would prove redundant to earlier work and experience conducted with this patient population. Therefore, in place of the focus groups (Task 1a, 1b and 1c) staff regularly met with the study interventionists in order to develop and tailor the intervention material. The training of project therapists (1d) was completed as scheduled. Though questionnaires and therapist materials were completed as scheduled (1e), there was some delay and in the production of recruitment materials due to nature of the multi-site IRB approval process. Materials have included posters, letters (signature stamped by prospective participant's oncologists), pamphlets, and stickers to be attached to eligible patients medical charts. Currently all recruitment materials have been approved.

Though recruitment (2a) has begun, there was approximately a 4-month delay in start-up due to multiple protocol amendments, and their respective DoD and multi-site IRB approval requirements. Study questionnaires and conducting of intervention sessions (2b, 2c) commenced after the start-up delays, and has kept pace with recruitment. The PI and Project Manager have begun regular therapist supervision (2d) with the interventionists throughout the year. Data entry (2e) has been done concurrently with recruitment and intervention sessions. Project 4 staff has worked closely with the Informatics Core in order to develop data entry protocols, computerized data entry form screens, and a system which allows Project 4 staff to be automatically notified when different questionnaire elements are due to be sent to patients. Follow-up assessments and treatment integrity checks (2f, 2g) are being conducted on a regular basis. Intervention sessions are audio taped for treatment integrity-tracking purposes.

Sluggish recruitment continues to be a significant issue in the third active year of the Project 4. Identification and recruitment figures continue to be lower than originally anticipated. Low recruitment figures continue to stem from two primary causes; 1) we have identified fewer eligible individuals than previously estimated, and 2) we have experienced a higher refusal rate than anticipated. Below, in Figure 1, we summarize our recruitment efforts to date. Our sample size at this point is 34. 18 women have been assigned to the Communication and Support skills condition and 13 women have been assigned to the supportive condition. Of the 18 women assigned to the Communication and Support skills condition, ten have completed all six sessions and five have dropped out of study. Of the 13 assigned to the Supportive counseling condition, seven women have completed all 6 sessions and five have dropped out. Twenty-two of our 34 participants have completed the first follow up and eleven have completed the second follow up survey.

Figure 1: Summary of Recruitment Efforts through 9-2003



In terms of other study tasks, all session audiotapes are being coded for integrity by Dorothy Weber, our quality analyst. All study data has been entered to date, and supervision of study therapists has been both ongoing via feedback from Sandra Corbett to each therapist as well as accomplished by in person supervision meetings every 3-4 months.

KEY RESEARCH ACCOMPLISHMENTS

- Attend and participate in monthly Center meetings.
- Actively recruiting patients, both at FCCC and satellite sites.
- Actively administering the experimental interventions.
- Further development and tailoring of the interventions.
- Trained the interventionist.
- Further development of the recruitment procedures.
- Finalization of study assessment instruments.
- Utilized Informatics Core to develop and maintain data collection and management procedures.

REPORTABLE OUTCOMES

Aside from our recruitment activity, summarized in Figure 1, we do not have additional reportable outcomes at this point.

CONCLUSION

Task 1 study elements have been completed. Task 2 elements, including recruitment, intervention, treatment integrity and supervision, and data collection and entry are well underway. In the last three years we have made significant efforts to boost enrollment by adding a number of local hospitals to our study as well as by increasing awareness of our project among the oncologists treating patients at Fox Chase Cancer Center. This effort has addressed some of the enrollment problem but because we are dealing with a very ill population it is likely unrealistic to expect a high enrollment. We have made efforts to reduce study burden by reducing questionnaire length and adding subject incentives, to reduce refusal rates. We estimate that preliminary data analysis will begin sometime in the next reporting year (10/2004-10/2005). Thus, no analytical conclusions can be drawn at this time.

REFERENCES

None

DOD Progress Report
Leadership Core

Dr. Suzanne M. Miller, Ph.D.
Principal Investigator
Core Director

Psychosocial and Behavioral Medicine Program
Division of Population Science
Fox Chase Cancer Center

INTRODUCTION

Under the direction of the Leadership Core, the development of the Behavioral Center of Excellence in Breast Cancer (BCE) has been guided by a unifying cognitive-affective processing (CAP) approach to breast cancer prevention and control that has informed the specific hypotheses of each project and has dictated the relevant interventions and assessments, and that provides a multidisciplinary linkage across projects. The senior leadership and administrative support core component is designed to ensure scientific collaboration, guidance, and integration across the research projects and to promote the efficient administration of all the components of the BCE grant. Through collaboration between the principal staff on the main projects and other cores, the Leadership Core is able to broaden past and ongoing research by pursuing a closely coordinated research program to modify attitudes, behavior patterns, and lifestyles in ways that will ultimately reduce breast cancer incidence, morbidity and mortality effectively, thus directly addressing the mission for consequential behavioral research in breast cancer.

The specific aims of the Leadership Core are as follows:

Aim 1: To provide oversight, and management of, all aspects of the BCE to maximize the efficiency of its integrative, inter-coordinated organizational structure.

The Leadership Core for the BCE is intended to be a resource to the Center as a whole, as well as to function as the administrative resource for each of the individual projects.

Aim 2: To continue to develop, refine, and evaluate the overarching, unifying conceptual framework.

In order to continually refine the guiding theory of research within the BCE, the Leadership Core will integrate data across projects to more comprehensively address the dynamics of the interactions between construals and the other cognitions and affects that they prime and activate within the processing system, as the individual interprets, transforms, and acts on diverse types of cancer risk information (Miller & Diefenbach, 1998).

Aim 3: To oversee and enhance the centralized quality control mechanism for designing, refining, and evaluating the theoretically derived assessments and interventions.

The Leadership Core will function to ensure that the project investigators create and tailor the CAP interventions to target the entire pattern of intervening cognitive and affective dynamics that underlie effective modulation of distress and long-term adherence to breast cancer prevention-control behaviors.

Aim 4: To develop actuarial predictive indices of cognitive-affective processing types.

With oversight from the Leadership Core, a goal of the BCE is to clarify and harness Person x Situation interactions emphasized by the C-SHIP model. This requires a shift from global to specific, contextualized analysis and assessments.

Aim 5: To oversee and guide the planning, development, and implementation of new BCE projects.

By building on the strong network of projects already proposed, the vision of the BCE is to develop further studies that are relevant to the CAP agenda and that interact synergistically with the ongoing work.

Aim 6: To administer the Training Program.

The Leadership Core will oversee the implementation of the pre- and post- doctoral training program through the identification of qualified candidates with ambitions to pursue careers in behavioral medicine and the development of communications to enhance cancer prevention and control.

BODY

According to our Statement of Work the plan during Years 2 through 3 was to accomplish the following tasks: 1) to convene Advisory Committee and scientific meetings; 2) to oversee implementation of core functions and to oversee initiation of projects and cores; 3) to implement the Training Program and, 4) implement meta-analysis and thematic integration of findings

Task 1. To convene advisory committee and scientific meetings.

The External Advisory Committee, which was chosen to provide consultation for the BCE senior staff, held its first meeting in December 2002 at FCCC. The Committee is not scheduled to reconvene until the fourth year of BCE funding.

Second, Dr. Miller, Director of the BCE, spearheaded the organization of the Behavioral Oncology Interest Group at the American Society for Preventive Oncology (ASPO). The second annual Behavioral Oncology Interest Group sponsored a Study Group Breakfast in March 2003. Dr. Miller and other members of the BCE Leadership Core joined forces with the Institute of Medicine National Cancer Policy Board to hold a joint breakfast for the Behavioral Oncology and Tobacco Interest Groups. Prior to the annual ASPO conference, IOM's National Cancer Policy Board released a report entitled, "Fulfilling the Potential for Cancer Prevention and Early Detection" which included a detailed analysis of the potential reductions in morbidity and mortality from modification of behavioral risk factors related to tobacco, diet, and physical activity as well as participation in recommended screening for early detection; a complete review of the treatment outcome literature for these target behaviors, an assessment of current practice in health care related to delivery of proven interventions, and an assessment of funding initiatives. The report also made a series of policy recommendations for federal and private sector initiatives to increase the rates of adoption, the reach, and the impacts of evidence-based cancer prevention and early detection. The focus of the breakfast session was a highlight of the 12 recommendations made in this report, followed by a panel discussion of the recommendations and an executive summary. Results from these meetings, which focus on the standard for state-of-the-science behavioral research in behavioral oncology, were published in *Cancer Epidemiology, Biomarkers, and Prevention* (see publications below) in 2004.

In addition, Dr. Miller is currently organizing a Pre-Conference to be held at this year's Society for Behavioral Medicine meeting. This meeting will consist of talks beginning with behavioral science continuing to the application of behavioral science in the clinical arena. The four speakers will be followed by roundtable discussions facilitated by behavioral scientists. The speakers and the topics on which they will present are described as follows:

- **Jennifer Lerner – Department of Social & Decision Sciences, Carnegie Mellon University:** Will emphasize affective and social dimensions of decision making and decision support and will relate this approach to cancer-related decision making.
- **Hillary Llewellyn-Thomas – Professor of Center for Evaluative Clinical Sciences, Center for the Evaluative Clinical Sciences, Dartmouth Medical School:** Will give an overview, and also talk about her work at the Dartmouth Shared Decision Making Center with respect to decision science and decision making, particularly as it relates to the cancer context, given her expertise in patient preferences for, and attitudes towards, treatment alternatives and involvement in treatment decisions; will share her thoughts of how patients understand the risk/benefit probabilities involved in different treatment options.
- **Peter Ubel - Director of the Program for Improving Health Care Decisions, University of Michigan School of General Medicine -** Will talk about his work with respect to decision science and decision making in the cancer context, bringing in a values perspective and bioethics considerations related to shared decision making, both for individuals and health care providers, given his perspective and expertise in cognitive-affective processing, bioethics, economics, and internal medicine.
- **Karen Sepucha, Senior Scientist in the Health Decision Research Unit at Massachusetts General Hospital in Boston, Instructor in Medicine, Harvard Medical School; Assistant in Medicine:** Will talk about models of delivery to support shared decision making in general, with examples both from your own work and that with Health wise, as well as public health implications of state-of-the-science in decision-making with respect to health management on a broad scale.

Third, the Leadership Core has established the Behavioral Medicine Speakers Series at Fox Chase Cancer Center. The following speakers were invited to present their most current data to the Division of Population Sciences:

- **Robert Schnoll, Ph.D., Fox Chase Cancer Center,** spoke on “FCCC Tobacco Control Program: Recent Findings and Future Research” on July 20, 2004
- **Carolyn Fang, Ph.D., Fox Chase Cancer Center,** spoke on “Psychosocial Interventions to Enhance Health” on August 31, 2004.
- **Catherine Wang, Ph.D., University of Michigan School Of Public Health,** spoke on “Facilitating Informed Decision Making for BRCA ½ Testing: From Theory to Practice” on October 26, 2004

- **David Buchanan, Ph.D., Research Fellow, National Cancer Institute, Public Health Ethics Behavioral Interventions Professor, Community Health Education, School of Public Health & Health Sciences, University of Massachusetts, Amherst**, spoke on "Quality of Life & Models for Evaluating" on November 2, 2004

Fourth, in September 2004, investigators within the FCCC Community Clinical Oncology Program (CCOP) Research Base convened to discuss the expansion of hospital-based research into the community. Through the simulation of research efforts into the community, the FCCC CCOP Research Base will provide cancer patients, their families, and high-risk individuals access to new prevention and control studies closer to home. At this meeting, CCOP investigators discussed the community implementation of an intervention for breast cancer survivors using the NCI publication *Facing Forward*.

Finally, Dr. Miller recently became a member of the Board of Directors of the New Jersey Health Care Quality Institute and has recently been appointed as a member of the National Quality Forum's *Quality of Cancer Care Measures* project where she serves on the Symptom Management/End of Life Care Technical Panel. In addition to symptom management and end-of-life care, this project focuses on colorectal and breast cancer diagnosis and treatment. The Technical Panel is charged with conducting an initial assessment to evaluate candidate performance measures for their validity, which must occur before the Project's Steering Committee will consider recommending the measure to the National Quality Forum for endorsement. A one-day organizational meeting will be held in November or December 2004, followed by a two-day measures assessment meeting in July or August 2005. Relevant findings and experiences gained from implementation and evaluation of BCE studies will inform proceedings.

Task 2. To oversee implementation of core functions and to oversee initiation of projects and cores.

The Leadership Core continues to hold monthly BCE meetings. Principal Investigators, Co-Investigators, Project Managers of the various BCE projects and Core staff attend these meetings that provide an opportunity for investigators to exchange ideas and provide input across studies. Agenda items include: 1) Updates from each project and core; 2) Training Program status; 3) DoD reporting requirements and IRB documentation; 4) Standardization of assessment tools across studies to maximize opportunities for meta-analysis; and 5) Cooperative strategies to enhance recruitment across studies. Meetings minutes are kept to record the current status of each study. Specifically:

- Recruitment for Phase 2 of Project 1 has begun. Ads have been sent to local Philadelphia radio stations and newspapers for 2-week time slots for two separate time periods. An amendment had been submitted and approved by FCCC IRB to exclude the criteria pertaining to one's income.
- Recruitment for Project 2 is still in progress. 12-month follow-up HHQ has been finalized with input from the Core, especially on health behavior questions (e.g., alcohol use). The FCCC IRB, the local IRB, and the DOD has approved the addition of Virtua as a recruitment. Recruitment is beginning at the site.

- The original protocol for Project 3 has been revised and the FCCC IRB has approved all revisions. Recruitment for the pilot study portion of the study is scheduled to begin upon approval from the DOD.
- Recruitment for Project 4 is still in progress. Identification and recruitment figures continue to be lower than originally anticipated. The staff continues to recruit all eligible patients and collect first and second follow-up surveys.
- Monthly BCE meetings were instrumental in the revision of the intervention protocol for Project 3. The FCCC IRB has approved a draft of the revision to the intervention and the revised protocol has been sent to the DOD for approval.

Task 3. To implement the Training Program.

The following has been implemented to support the BCE Training Program:

Three FCCC faculty members serve on a BCE Fellowship Search Committee who were selected by members of the Leadership Core. This committee holds the responsibility of disseminating an announcement about pre- and post-doctoral fellowship opportunities, developing an evaluation procedure, arranging for candidate interviews, and selecting candidates. The committee is comprised of Dr. Robert Schnoll, Dr. Mary Daly, and Dr. Eric Ross, who meet over the course of the year to devise fellowship announcements and candidate review criteria. The following review criteria are used to evaluate potential candidates: Ability in Written Communication, Familiarity with Behavioral Oncology in General, Familiarity with Breast Cancer in Particular (Behavioral and Medical issues), General Research Experience, Apparent General Research Proficiency, Commitment to Research Career in Behavioral Oncology/Cancer Prevention and Control, Quality and Relevance of Academic Training, Enthusiasm for Fellowship, Convergence Between BCE Projects and Applicant's Experience, Convergence Between BCE Projects and Applicant's Career Goals.

Pagona Roussi, Ph.D., returned to the Psychosocial and Behavioral Medicine Program in September/October 2004. Dr. Roussi will be serving as a consultant to Dr. Miller and members of the research team on several ongoing grants. Dr. Roussi comes from Aristotle University of Thessaloniki, Thessaloniki, Greece offering expertise in stress and coping with major life events, with a special interest in serious illnesses. Dr. Roussi has a Ph.D. in Chemistry earned at Imperial College, London University, London, England in 1977. Since earning her Ph.D. in Clinical Psychology at Temple University, Philadelphia, Pennsylvania in 1995 Dr. Roussi has taught in the Department of Philosophy and Social Studies at the University of Crete, Crete, Greece as a Visiting Assistant Professor as well as in the Department of Psychology at Aristotle University of Thessaloniki, Thessaloniki, Greece. She has several publications, both independently and in collaboration with Dr. Miller and other Investigators. Her responsibilities at FCCC include analyzing data, writing manuscripts, and providing consultation and assistance with the designing of new interventions. Specifically, she will be involved in the development of the intervention protocol for Project 3.

Elizabetta Razzaboni, Ph.D., joined the Psychosocial and Behavioral Medicine Program in August 2004 and worked with the research team for eight weeks. She came to FCCC from the Department of Psychology at the University of Bologna, Bologna, Italy.

The Summer Internship Program continued to operate through Fall 2004. The Summer Internship program was established in 2002 to provide training opportunities to students at the high school, undergraduate and graduate levels in the area of behavioral research within the context of breast cancer prevention and control to encourage future leaders in the field and to provide a source of candidates for the Training Program. Two interns joined us in the summer of 2004: Lovely Jacobs, a senior attending Samuel S. Fels High School in Philadelphia, PA, joined FCCC in July 2004 as a participant in the Howard Hughes Student Scientist Program. She will continue to work with the FCCC research team through summer 2005, presenting her research to other Howard Hughes student scientists in January 2005. Julie Michael joined FCCC in May 2004 as a senior at Villanova University in May 2004 to fulfill the requirements for her Bachelors degrees in Comprehensive Science (B.S.) and Psychology (B.A.) with a concentration in Ethics in Health Care. Upon completing her 15-week internship, she was offered, and accepted, a part-time position in the department. Each intern was required to complete a web-based bioethics course, was provided with required readings highlighting the theoretical framework that guides our research, and was responsible for conducting study-related literature searches using electronic databases such as PubMed and Ovid as well as retrieving journal articles electronically and from FCCC's on-campus library.

Task 4. To implement meta-analysis and thematic integration of findings.

An extensive meta-analysis will be conducted, as planned in Task 4, upon the completion of data collection for the studies within the BCE.

The Leadership Core has contributed an extensive list of articles based on its literature search on breast cancer risk to the library of the Behavioral Research Core Facility (BRCF) at Fox Chase Cancer Center under the direction of Dr. Suzanne Miller. The BRCF provides the necessary infrastructure and resources to integrate basic and applied biobehavioral and psychosocial research across the spectrum of cancer prevention and control research. Its mission and function are synergistic with that of the BCE. The BRCF library serves as an NCI- funded resource to investigators throughout the institution.

KEY RESEARCH ACCOMPLISHMENTS

- The continuation of monthly BCE meetings.
- The following steps have been implemented to support the BCE training program:
 - The continuing support of the BCE Training Program Committee that oversees the development and implementation of promotional strategies to enhance recruitment of qualified candidates for the pre- and post-doctoral fellowships.
 - Pagona Roussi, Ph.D., returned to the Behavioral Medicine Program as a consultant on the various projects within the BCE.

- Elizabethta Razzaboni, Ph.D., joined the Behavioral Medicine Program in August 2004 as a visiting researcher providing consultation in qualitative data analysis for the projects within the BCE.
- Interviews continue to be conducted to fill the remaining post-doctoral position within the Training Program.
- The Summer Internship Program continued successfully for its third year in providing training opportunities to students at the high school, undergraduate and graduate level in the area of behavioral research within the context of breast cancer prevention and control to encourage future leaders in the field.
- The continuation of the Behavioral Oncology Interest Group at the American Society for Preventive Oncology (ASPO).
- Preparation and publication in 2004 of two volumes that will extend the theoretical model across the cancer continuum, including genetic risk, and provide an integrative synthesis of the behavioral medicine field.
- Collaboration with Al Marcus, Ph.D., of the AMC Cancer Research Center, on a research consortium using the Cancer Information Service.

REPORTABLE OUTCOMES

At this time, the Leadership Core continues to provide integrative oversight and management of all aspects of the BCE to maximize the efficiency of its inter-coordinated organizational structure. The Core continues to develop, refine, and evaluate the overarching, unifying conceptual framework in its efforts to oversee and enhance the centralized quality control mechanism for designing, refining, and evaluating the theoretically-derived assessments and interventions. The Core remains active in the ongoing maintenance of the Training Program.

- Presentations:

Miller, S.M., Schwartz, M. Invited Presentation at the Cancer Genetics Studies Consortium Consensus Meeting. Paper on screening/prevention practices of individuals at risk: Building bridges from tantalizing research findings to future directions. Alexandria, VA, October, 2003.

Miller, S.M. 53rd Annual Meeting of the American Society of Human Genetics. Paper presented on: Genetic predisposition: Individual evaluations of risk. Part of Invited Session on: Genetic Risk Communication in Theory and Practice: Exploring the Possibilities. Los Angeles, CA. November, 2003.

Miller, S.M. Invited Speaker. Japan Foundation for Aging and Health. Mental Support for patient's with cancer. Kobe, Japan, February 2004.

Miller, S.M. Invited Speaker. University of the Sacred Heart. Presentation: Behavior and Cancer. Tokyo, Japan, February 2004.

Miller, S.M., Rodoletz, M., Daly, M.B., Roussi, P., Buzaglo, J., Godwin, A., Malick, J., Wang, H., Montgomery, S., & Spoltore, J. Impact of a Cognitive-Affective Preparatory intervention among high risk women undergoing breast/ovarian genetic testing. Poster presented at the 28th Annual Meeting of the American Society of Preventive Oncology, Bethesda, Maryland. March, 2004.

Miller, S.M., Roussi, P., Rodoletz, M., Daly, M.B., Sherman, K.A., Diefenbach, M.A., Buzaglo, J., & Godwin, A. Impact of an Enhanced Counseling Intervention Among High-Risk Women Undergoing Breast/Ovarian Genetic Testing. Poster presented at the Annual Meeting of the Society of Behavioral Medicine. Baltimore, Maryland. March, 2004.

Miller, S.M. Invited Speaker. The Second Annual Lynne Cohen Foundation Symposium on Women's Cancer: Defining the Roles of Genetics and the Environment. Presentation on: "Factors/Issues in Clinical Decision Making." New York, NY. April, 2004.

Miller, S.M., Stanton, L., Rodoletz, M., Daly, M.B., Sherman, K.A., Roussi, P., Wang, H., Godwin, A., Spoltore, J., Montgomery, S., & Michael, J. Facilitating health behaviors among women undergoing BRCA 1/2 testing. Presented at the Annual Meeting of the American Society of Clinical Oncology, New Orleans, Louisiana, June 2004.

Miller, S. M. 8th International Congress of Behavioral Medicine. Paper on: Tailoring Monitoring vs. blunting in the preparation for stressful medical procedures. Part of Invited Symposium on: Psychological Preparation for Medical Intervention. Mainz, Germany. August, 2004.

- Publications:

Miller, S.M. & Sherman, K.A.A. (2004). Cancer screening. In N. Anderson (Ed.) The Encyclopedia of Health and Behavior. CA: Sage Publications.

Sherman, K.A.A., Montrone, M., & Miller, S.M. (2004). Infertility. In N. Anderson (Ed.). The Encyclopedia of Health and Behavior. CA: Sage Publications.

Miller, S.M., Bowen, D. J., Campbell, M.K., Diefenbach, M.A., Gritz, E.R., Jacobsen, P.B., Stefanek, M., Fang, C.Y., Lazovich, D., Sherman, K.A., Wang, C. (2004). Current research promises and challenges in behavioral oncology: Report from the American Society of Preventive Oncology Annual Meeting. Cancer Epidemiology, Biomarkers and Prevention, 13, 171-180.

Miller, S.M. (in press). Applications of the Monitoring Process Model. Applied Psychology: An International Review.

Sherman, K.A.A., Miller, S.M., Sheinfeld-Gorin, S. (in press). Psychosocial determinants of participation in breast cancer risk counseling programs and screening regimens among African American women. In: Breast Cancer in African American Women. NY: Susan G. Komen Foundation and African American National Advisory Committee.

Schnoll, R.A., Miller, S.M., Wang, H., Babb, J.S., Cornfeld, M.J., Higman-Tofani, S., Henigan-Peel, T., Balshem, A., Slater, E., Ross, E., Boyd, S., Engstrom, P.F. (in press). Change in worksite behavior following cancer risk feedback: A pilot study. American Journal of Health Behavior.

Katz, M.L., Ruzek, S.B., Miller, S.M., Legos, P. (in press). Gender differences in patients needs and concerns to diagnostic tests for possible cancer. Journal of Cancer Education.

Miller S.M., Roussi, P. (in press). Psychosocial Factors Involved in Genetic Testing Decisions and Behaviors. Hellenic Journal of Psychology.

Miller, S.M., et al. (in press) Information processing in breast/ovarian genetic risk. Health Education and Behavior.

Miller, S.M., Fleisher, L., Schnoll, R.A., Rodoletz, M., Razabonni, E., et al. (in press) Facilitating Breast Cancer Genetic Counseling Referral through Information, Preparation, and Referral, Journal of the National Cancer Institute.

CONCLUSION

Members of the BCE continue to successfully assist all research teams accomplish their tasks during its second year. Our efforts have remained focused on the development of the necessary infrastructure between project staff and the other core facilities in order to facilitate synergistic research efforts and integrative findings across the multiple projects.

REFERENCES

None

DOD Progress Report
Informatics Core

Suzanne M. Miller, Ph.D., Principal Investigator
Eric Ross, Ph.D., Core Director

Psychosocial and Behavioral Medicine Program
Division of Population Science
Fox Chase Cancer Center

INTRODUCTION

The varied populations studied in this Behavioral Center of Excellence in Breast Cancer (BCE) and the complexity of the designs require development of study-specific computer based tools to provide critical project management and coordination, and for the collection, validation, storage, retrieval and analysis of data. The projects contained in this BCE include: Understanding Breast Cancer Risk Assessment and Screening Behavior Among the Underserved, Cancer-A Teachable Moment Within the Family: From Concept to Community, Facilitating Re-entry Following Treatment for Primary Breast Cancer, and Impact of a Communication Skills versus a Supportive Therapy Intervention for Women with Metastatic Breast Cancer.

The objective of this core is to facilitate the research conducted in this BCE by providing (1) a central repository for all of the data included in the research, (2) data entry and validation services and (3) report generation and standard statistical program services. To be included in this core data repository are: a) socio-demographic data on study populations, b) clinical information, c) family history, d) genetic testing data, e) psycho-social data, f) health history data, g) quality of life data, h) cancer screening data, and i) diet data. Data from approximately 1000 subjects collected in four research projects will ultimately be stored in this information system.

The specific aims of the core are:

Aim 1: To provide computer-based tools that facilitate the entry, storage, manipulation and retrieval of the large quantities of data generated in the proposed research.

Aim 2: To ensure the accuracy of the data maintained in the database by developing human and software based data consistency and quality control systems.

Aim 3: To provide high-quality data entry services.

Aim 4: To organize and maintain the database to maximize accessibility, while maintaining strict confidentiality.

Aim 5: To provide statistical computing support.

BODY

Below, we specify the tasks to be accomplished in the context of this project.

Task 1. Provide computer-based tools that facilitate the entry, storage, manipulation and retrieval of the large quantities of data generated in the proposed research. (Months 1-47)

- a. In collaboration with the project investigators and research teams clearly define the specifications of the required information systems
- b. Carefully design the needed database structures
- c. Develop database systems
- d. Design, and develop electronic data entry/retrieval systems
- e. Test the electronic data entry/retrieval systems

- f. Design and develop report and letter generation software
- g. Test report and letter generation software
- h. Review of applications by Project Investigators
- i. Make modifications as needed. Put software into production
- j. Support and enhance software system software as needed

Task 2. Ensure the accuracy of the data maintained in the database by developing human and software based data consistency and quality control systems. Provide data entry and data validation services. Provide statistical computing support. (Months 3-48)

- a. In collaboration with the project investigators and research teams design, develop and test data quality assurance systems
- b. Conduct data entry and data validation
- c. Provide statistical programming services

KEY RESEARCH ACCOMPLISHMENTS

- Core staff attend and participate in monthly Center meetings.
- Core staff collaborated with project investigators and research staff to refine the data flow and hardcopy data collection instruments for Projects I, II and IV. Core staff developed data dictionaries based on study requirements and data collection instruments.
- Core personnel have designed and developed comprehensive information management systems to meet the specific needs of projects I, II and IV. These customized relational database systems have been implemented using ORACLE database software. The database and management structure facilitate efficient data capture and manipulation, as well as control the exchange of information across the projects. All software has undergone thorough testing before release to the user community.
- Client-server and web-enabled electronic data entry/retrieval and report generation software have been developed for Projects I, II and IV using Oracle's Developer/2000 suite of products.
- Data quality assurance procedures have been implemented for Projects I, II and IV, using software-based data entry checks as well as post-entry manual audits.
- Software for the scheduling of follow-up visits, and the distribution of mailed self-report questionnaires has been developed for Project II.
- Software was developed, for Projects I, II and IV, to generate reports that allow tracking of study accrual and progress of individual study subjects.
- All FCCC computers used for storing the information were protected from inappropriate outside access by the FCCC firewall.

- Security measures for accessing data have been implemented. The first level controls access to the desktop computers and web-server. Fox Chase Cancer Center uses a Lightweight Directory Access protocol (LDAP) directory service, implementing a subset of the InteOrgperson/EduPerson V2.0 schema, to provide a robust, extensible, and well-controlled common authentication mechanism. The second level of username/password based security takes place at the database server and application interface level. Each user is assigned a unique Oracle username/password. Restrictions are applied to each user commensurate with their needs to access the data (roles) at the application level.

REPORTABLE OUTCOMES

The details of the information system developed for the three research projects are described below.

Project I: Understanding Breast Cancer Risk Assessment and Screening Behavior among the Underserved

The overall goal of Project I is to identify and assess barriers and facilitators to participation in breast cancer risk assessment and adherence to breast cancer screening recommendations among African American women.

Core staff collaborated with project investigators and staff to refine and finalize the data flow and telephone data collection instruments. Core staff used a case tool (PowerDesigner 6.1.0) to model the database, represent the physical organization of data in a graphic format, generate database creation and modification scripts, define referential integrity triggers and constraints, generate extended attributes, and generate a data dictionary. Core staff designed and developed a Computer Assisted Telephone Interview (CATI) system to meet the specific needs of this the study. The application calculates each participant's estimated risk of developing breast cancer through an interface with a FORTRAN implementation of Mitchell Gail's algorithm. A graphical user interface (GUI) system for displaying and scheduling follow-up phone interviews was developed and is currently being used by project staff.

Project II: Cancer – A Teachable Moment within the Family: From Concept to Community

The goal of this study is to test the effectiveness of a tailored intervention to increase participation rates in a FCCC high-risk breast cancer program (i.e., FRAP). A secondary aim is to explore the effect of the intervention on breast cancer screening practices.

Core staff collaborated with project investigators and research staff to refine and finalize the data flow and hardcopy data collection instruments. The relational database management system for this project is complete. This system will maintain all of the information collected in this study including: health history, clinical, epidemiologic, socio-demographic, and psychosocial data. In addition, this database contains cancer and vital status data on relatives of individuals recruited into the study. The software system coordinates numerous tasks, including the scheduling of follow-up visits, and the

distribution of mailed self-report questionnaires. This system generates multigenerational pedigrees from the union of family histories provided by two or more distinct study subjects in the same family. The family data can be updated from follow-up information to include deaths or new cancers reported for study subjects, previously listed family members, as well as new births. The system randomizes participants to study arm based on strata defined by the participant's MBSS score, her family history (of cancer) and date of last mammogram. Tailored and control scripts are automatically generated at time of randomization using Oracle Reports. Core staff also developed: a ticker/reminder system to notify appropriate staff when a 12-month follow-up phone survey is due; report generation software to produce printed materials (dependant upon study arm assignment) and accompanying cover letters; and database views that are used by project staff to display information about study participation. All software has undergone thorough testing.

Project III: Facilitating Re-entry Following Treatment for Primary Breast Cancer

The primary objective of this study is to develop and evaluate a C-SHIP guided Cognitive-Affective Processing (CAP) intervention to facilitate psychosocial adjustment at re-entry, following adjuvant treatment for primary breast cancer. Core staff reviewed draft data collection instruments and project timelines. Project III has completed Phase I focus groups to help refine the cognitive-affective intervention. Design, development, testing and deployment of the production database for the randomized trial has been completed and the data collection instruments and study timelines have been finalized. Data collection and management will begin upon receipt of DOD approval of revisions.

Project IV: Impact of a Communication Skills versus a Supportive Therapy Intervention for Women with Metastatic Breast Cancer

The goal of this study is to compare a cognitive-behavioral intervention (with a communication and support training focus) to a supportive therapy intervention, on the quality of life of women with metastatic breast cancer. A secondary aim is to explore moderating effects of individual dispositional factors and mediating effects of support-related variables on the impact of the intervention strategies.

The relational database management system for this project has been completed. This system maintains all of the information collected in this study and facilitates many aspects of data collection and patient tracking. Core staff collaborated with project investigators and research staff to refine and finalize the data flow and hardcopy data collection instruments. Data dictionaries were prepared by Core staff. PowerDesigner was used to model the database, represent the physical organization of data in a graphic format, generate database creation and modification scripts, define referential integrity triggers and constraints, and generate a data dictionary. A system for the scheduling of follow-up visits and electronic screens displaying subjects due for follow-up was also developed. All software has undergone thorough testing by demonstrating that each function is operational and performs according to specification. Views of the database have been created to facilitate analysis by investigators and study biostatisticians using SAS and SPSS.

CONCLUSION

This Core will serve as a resource for the Center of Excellence as a whole and will maintain a valuable source of data for current and future studies. By centralizing these services into an Informatics Core, we will be better able to manage and coordinate the collection, storage, and distribution of a large amount of highly valuable data. Subject to informed consent, the information contained in the data repository will be available to all investigators in the Center of Excellence. By providing access to the data to all participants, sharing technical capabilities and ensuring the quality of the data, this core will not only facilitated achievement of the aims of the individual projects, but also make possible exploratory analyses beyond the stated aims of the projects.

REFERENCES

None

DOD Progress Report
Communications Core

Suzanne M. Miller, Ph.D., Principal Investigator
Linda Fleisher, MPH, Core Director

Psychosocial and Behavioral Medicine Program
Division of Population Science
Fox Chase Cancer Center

INTRODUCTION

The Communications Core has provided critical support and services for the research projects in the Behavioral Center of Excellence in Breast Cancer (BCE). The Communications Core builds on and extends the infrastructure, resources and expertise of the FCCC Behavioral Core to include state-of-the art communications theory and applications.

The Communications Core has two primary functions. The first, descriptive function consists of assessing information needs and culturally specific beliefs of populations targeted by the different Center projects. The second primary function of the Communications Core is to successfully translate this information into effective communication messages and strategies that meet the needs of the target population. To this end, the Communications Core conducts in-depth needs assessments of the target populations through focus groups for each individual research project; analyze the information obtained; and assist in developing appropriate patient-tailored health communications.

Specifically, the aims of the Communications Core are:

Aim 1: To provide linkages to the FCCC Behavioral Core for assistance in evidence-based behavioral approaches and measures.

Aim 2: To expand the Behavioral Core resources to include communication theory and applications.

Aim 3: To facilitate the assessment of information needs of the target populations through focus groups.

Aim 4: To provide consultation in the development of interventions using behavioral, health education and communication principles and theories.

Aim 5: To provide formative evaluation services (e.g. implementation and analysis) to inform the development and pilot testing of interventions for specific populations.

By utilizing the Communications Core for all research projects an economy of scale is created with a synergistic impact that benefits and informs each of the projects as well as the entire Behavioral Center of Excellence.

These goals are achieved through a structured consultation and implementation process that includes an initial contact and needs assessment phase, a planning phase, and an implementation and follow-up phase. Throughout these phases, members of the Communications Core and members of the individual research projects have been in frequent contact to ensure that the objectives of the individual research projects are achieved.

BODY

In year 3 the Communications Core initiated the various tasks for each research project as specified in the Statement of Work and as listed below. The specific tasks by research projects were. The specific tasks by research projects are:

Project I: Understanding Breast Cancer Risk Assessment and Screening Behavior Among the Underserved.

The major task for Project 1 was to complete the refinement of the psychosocial familial risk questionnaire for low-income African American women. Specifically:

Completed assessment instrument Month 1-3

Project II: Cancer-A teachable Moment Within the Family: From Concept to Community

Reviewed final materials for project Month 1-3

Project III: Facilitating Re-entry following Treatment for Primary Breast Cancer

Assisted in the development of analysis plan for focus groups Month 2-6

KEY RESEARCH ACCOMPLISHMENTS

- Attend and participate in monthly Center meetings.
- Members of the Communications Core have continued to augment the library of the Behavioral Research Facility with articles from the communications literature. This resource is made available to all members of the BCE, as well as the wider community of researchers at FCCC. Further, project-specific accomplishments follow:
- **Project I.** In collaboration with project staff the Communications Core has completed focus groups analyses.
- **Project II.** The Core met a number of times with the research team to review the final materials (tailored messages and counseling protocol).
- **Project III.** Members of the Communications Core have regularly met to develop an analysis plan for the focus group data.
- **Project IV.** The research team and members of the Communications Core have provided additional strategies to recruitment.

REPORTABLE OUTCOMES

Other than the key research accomplishments detailed above there are no reportable outcomes.

CONCLUSION

Members of the Communications Core have successfully assisted all research teams accomplish their tasks during their third year. Our efforts have focused on finalizing assessment and materials and analysis of focus group data to inform study procedures, protocols and materials. The Core has provided ongoing feedback at the monthly meetings and provided strategies for recruitment. We have also continued to add to the BRCF library by identifying and including key health communication research articles.

REFERENCES

None

DOD Progress Report
Blood Collection and BRCA1 and BRCA2 Mutation Testing through the Genetic Susceptibility-
Testing Laboratory Core

Dr. Suzanne M. Miller, Ph.D., Principal Investigator
Andrew K. Godwin, Ph.D., Core Director

Psychosocial and Behavioral Medicine Program
Division of Population Science
Fox Chase Cancer Center

INTRODUCTION

The strongest known epidemiological risk factor for breast cancer is a positive family history and studies of breast and ovarian cancer patients and their relatives consistently find statistical evidence for involvement of autosomal dominant genes. Therefore, the identification of specific genes has long been the focus of efforts to identify women at high risk. A promising approach for reducing the high incidence and mortality associated with breast cancer lies in the early detection of women at high risk. These women, once identified, can be targeted for more aggressive preventative programs and tailored interventions to help cope with their increased risk of developing cancer. As a result of the cloning of the two most prominent breast-ovarian cancer susceptibility genes, *BRCA1* and *BRCA2*, it is now possible to screen women from high-risk families for germ-line mutations. This Core was created to support Project 2, "Cancer-A Teachable Moment Within the Family; From Concept to Community" and Project 3, "Facilitating Re-entry following Treatment for Primary Breast Cancer". Project 2 proposes to test the efficacy of a health communication message personalized to a set of demographic, clinical, and psychosocial factors and timed to capitalize on the heightened awareness of breast cancer risk attributed to the recent diagnosis in a first-degree relative (FDR). The purpose of the health communication message is to encourage that these at-risk women participate in the Family Risk Assessment Program at FCCC or the Network Hospitals in order to receive personalized breast cancer risk information provided to the participants. *BRCA1* and *BRCA2* mutation analysis is offered to those who have familial patterns of breast cancer indicative of a possible involvement of a disease-associated germline mutation. Similarly, Project 3 proposes to provide tailored communications. However, the communications are provided to breast cancer patients actively undergoing treatment. The communications are designed to enhance adjustment, quality of life, and adherence to recommended follow-up regimens during survivorship. Participants are extended an offer to participate in FRAP to receive familial risk information. Eligible participants, based again on family history of breast cancer, are offered *BRCA1* and *BRCA2* mutation analysis.

Specifically, the aims of the Core are as follows:

Aim 1: To collect and bank blood samples from women with breast cancer or unaffected women with a family history of breast cancer as part of Projects 2 and 3.

Aim 2: To evaluate constitutive DNA from individuals participating in the Projects 2 and 3 for mutations in *BRCA1* and *BRCA2*.

We have an extensive history of collecting and banking biospecimens from women at an increased risk for breast and/or ovarian cancer at the Fox Chase Cancer Center. During the past year we collected and processed blood samples from hundreds of FRAP participants and have screened for germline mutations in *BRCA1* and *BRCA2*. We have improved our methods to identify germline mutations as well as to assess the impact of these mutations on cancer risk. To date, we have identified more than 500 *BRCA1* and/or *BRCA2* mutation carriers (including 63 unique deleterious mutations) using our EMD approach. The personnel and methodology are in place to handle and screen the BCE samples as they are obtained. We attend the monthly BCE meetings to discuss recruitment and to up date the progress we have made in our genetic testing.

BODY

The strongest known epidemiologic risk factor for breast cancer is a positive family history and studies of breast and ovarian cancer patients and their relatives consistently find statistical evidence for involvement of autosomal dominant genes. Therefore, the identification of specific genes has long been the focus of efforts to identify women at high risk. A promising approach for reducing the high incidence and mortality associated with breast cancer lies in the early detection of women at high risk. These women, once identified, can be targeted for more aggressive preventative programs and tailored interventions to help cope with increased risk. As a result of the cloning of the two most prominent breast-ovarian cancer susceptibility genes, *BRCA1* and *BRCA2*, it is now possible to screen women from high-risk families for germ-line mutations. We developed this Core base on our previous experiences in effectively collecting thousands of blood samples from research participants with family histories of breast and/or ovarian cancer, and in screening for mutations in *BRCA1*, *BRCA2*, and other candidate breast cancer susceptibility genes. This Core supports Projects 2 and 3 (as well as the other Project in the BCE if the need arises), by providing a highly accurate and cost-effective means for testing eligible participants for mutations in the two most prominent breast cancer susceptibility genes, *BRCA1* and *BRCA2*.

KEY RESEARCH ACCOMPLISHMENTS

- Improved the ability to detect *BRCA1* and *BRCA2* mutations in genomic DNA.
- Reduced the cost of full *BRCA1* and *BRCA2* mutation analyses to a third of the cost of commercial testing without loss of sensitivity.
- Created *BRCA1* and *BRCA2* exon chips for detection of genomic rearrangements in these two genes.
- Included mutation detection technology for large deletions/insertions in *BRCA1*, an extension of PCR based mutation detection.
- Identified novel polymorphisms common to ethnic populations; accruing variants of uncertain significance novel to ethnic populations.

REPORTABLE OUTCOMES

- Abstracts

*=supported by DAMD17-01-1-0238 ("Tailored Communications to Enhance Adaptation Across the breast Cancer Spectrum")

**=Demonstrates refinement and application of our methods to detect germline mutations in high-risk individuals.

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CONCLUSION

The work that we have preformed during the first three years of this application has served to improve our ability to detect mutations in the two prominent breast cancer susceptibility genes, *BRCA1* and *BRCA2*. We have published our mutation detection method and have shown that it

is comparable if not superior to commercial methods at a significantly lower cost. We have also developed a method to detect large genomic rearrangements in *BRCA1* and *BRCA2* that elude detection when using PCR-based approaches to search for mutations. We are also developing in our testing regimen a PCR based method for detecting large insertions/deletions in *BRCA1*. Overall, we are in optimal position to appropriately analyze any and all BCE samples once they become available through Projects 2 and 3. Furthermore, we will be able to process more samples than originally proposed due to our technical improvements and ability to automate the method.

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None